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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/366,458 08/03/99 DREYER

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HM12/0731  
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EXAMINER

HUNT, J

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

07/31/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/366,458**

Applicant(s)

**Dreyer**

Examiner  
**Jennifer Hunt**

Art Unit  
**1642**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above, claim(s) 11-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election of Group I, claims 1-10 Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-49 are pending in the application. Claims 11-49 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 1-10 are considered herein.

### ***Specification***

3. The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable code. (see MPEP 608.01(p)).

Appropriate correction is required.

### ***Claim Rejections - 35 U.S.C. § 112***

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4. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. The term "substantially enriched" in claims 1-10 is a relative term which renders the claim indefinite. The term "substantially enriched" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It cannot be considered "substantially enriched" and what would not.
6. Claims 1-10 are unclear in the recitation of "binding agent". The metes and bounds of a "binding agent" cannot be determined. It is not clear what would be considered a "binding agent" and what would not.
7. Claims 1-10 are unclear in the recitation of "serpentine cell surface marker". The metes and bounds of a "serpentine cell surface marker" cannot be determined. It is not clear what would be considered a "serpentine cell surface marker" and what would not. Serpentine receptors and markers are never defined in the specification such that their metes and bounds are clear.
8. Claims 2-3 are unclear in the recitation of a marker which is "associated with" a specific cell type. The metes and bounds of "associated with" cannot be determined. It is not clear what markers would be considered "associated with" and what markers would not.

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9. Claims 2-3 are unclear in the recitation of a marker which is “selecting for” an additional marker. The metes and bounds of “selecting for” cannot be determined. It is not clear what markers would be considered “selecting for” and what markers would not.

10. Claim 5 is unclear in the recitation of “or derivative thereof”. The metes and bounds of a derivative cannot be determined., It is not clear what would be considered a derivative and what would not. Additionally, it is not clear if derivative refers to the antibodies, ligands, or agents in general.

11. Claims 7-9 are unclear in the recitation of “analyzing the DNA”. The metes and bounds of analyzing DNA cannot be determined. It is not clear what type or nature of analysis is desired, not what said cells are being analyzed for.

12. Claims 7-9 are incomplete because they omit essential steps. See MPEP § 2172.01. While all of the technical details of the method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is practiced.

The minimum requirement for method steps should at least include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized and a correlation step describing how the results of the assay allow the determination. In the instant case, a step for “analyzing the DNA of the cells” is recited, but it is not clear how this analysis correlates to the method of producing a substantially enriched cell population, or what said analysis is intended to determine.

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13. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for sorting serpentine receptor positive cells from serpentine receptor negative cells, does not reasonably provide enablement for sorting any cell lineage by detecting a serpentine receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining scope and enablement are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented in the specification, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the relative skill of those in the art, 7) the predictability of the unpredictability of the art, and 8) the breadth of the claims (see *Ex parte Forman*, 230 USPQ 546, BPAI, 1986).

The claims are broadly drawn to a method of obtaining a composition substantially enriched in a specific cell type by selecting cells which express a serpentine cell surface marker. Thus the claims broadly encompass selecting for and isolating any "specific" cell type by binding an agent to a serpentine marker and isolating the cells which express that serpentine marker.

The specification prophetically teaches that serpentine receptors are expressed in various cell lineages and that they are in fact "lineage markers", indicative of what systems cells have evolved from. As support for these prophetic teachings, the specification provides very limited guidance as to the similarities between EST's which correspond to serpentine receptors in numerous and variant cell lineages, however there is no evidence that these markers are

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indicative of a particular cell lineage. They are not specific for a particular kind of cell, nor are they helpful in determining what type of cell a specific cell is, or from whence that cell evolved. Applicant has established that various EST fragments are repeated in various organ systems throughout the genome. No other guidance is provided, and no further conclusions can be drawn. Further, the data obtained by applicant, necessary to practice the invention, is improperly incorporated by reference as set forth above.

Thus there is no guidance or objective evidence that the instant method would be useful or functional for sorting specific cells, absent the sorting of serpentine marker positive cells from serpentine receptor negative cells.

Therefor one of skill in the art would not be enabled to practice the invention as claimed.

***Claim Rejections - 35 U.S.C. § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1-2, and 4-7 rejected under 35 U.S.C. 103(a) as being unpatentable over Nef and Nef, PNAS, Vol. 94, pages 4766-4771, April 1997, or Drutel et al., Receptors and Channels, Vol.

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3, pages 33-40, 1995, or Vanderhaeghen et al., Biochemical and Biophysical Research Communications, Vol. 237, pages 283-287, 1997, or Mombaerts et al., Cell, Vol. 87, pages 675-686, November 15, 1996, in view of Janeway and Travers, Immunobiology, pages 2:20-2:30, 1997, or Stites et al., Basic and Clinical Immunology pages 291-293, 1987, or Schlossman et al., Purification of B Lymphocytes, pages 313-315, 1973, or Seed et al., PNAS, Vol. 84, pages 3365-3369, May 1987, or Wysocki et al., PNAS, Vol. 75, No. 6, pages 2844-2848, June 1978, or Aruffo et al., PNAS, Vol. 84, pages 8573-8577, December, 1987, or Heller et al., PNAS USA, Vol. 94, pages 2150-2155, March 1997, or Foote, US Patent 5,661,628, August 26, 1997.

Nef and Nef teaches olfactory marker positive cells, and methods of identifying such, and that such cells have olfactory and neurologic function. Nef and Nef further teach DNA analysis of the olfactory positive cells, including Southern Blot analysis. (see for example, abstract). Drutel et al. teaches olfactory marker positive cells, and methods of identifying such, and that such cells function in olfactory development, sperm chemotaxis, and odor and taste recognition (see for example, abstract and page 33, first paragraph). Drutel et al. further teach DNA analysis of the olfactory positive cells. Vanderhaeghen et al. teaches olfactory marker positive cells, and methods of identifying such, and that such cells have olfactory function Vanderhaeghen et al. further teach DNA analysis of the olfactory positive cells. (see for example, abstract) Mombaerts et al. teaches olfactory marker positive cells, and methods of identifying such, and that such cells have olfactory and neurologic function. Mombaerts et al. further teach DNA



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analysis of the olfactory positive cells (see for example, abstract). Thus olfactory cells and their functions are known in the art.

Nef and Nef, Drutel et al., Vanderhaeghen et al., or Mombaerts et al. fail to teach sorting and enrichment of cells which express olfactory (serpentine) receptors.

Methods of cell sorting, purification and selection based on specific receptor expression are well established in the art. For example, Janeway and Travers, teaches methods of selecting specific cells and purifying those cells using immunohistochemistry, protein affinity purification, and FACS (including multiple markers, immobilized binding agents, monoclonal and polyclonal antibodies, as well as DNA analysis) (see pages 2:20-2:30). Stites et al. teaches methods of selecting specific cells and purifying those cells using FACS (including monoclonal and polyclonal antibodies and DNA analysis) (see pages 23291-291). Schlossman et al. teaches methods of sorting and purifying B-lymphocytes using polyclonal antibodies (see page 313). Seed et al. teaches methods of sorting using monoclonal antibodies, as well as DNA analysis and Southern Blot and including the cell adhesion molecule CD2. Wysocki et al. teaches methods of selecting specific cells and purifying those cells using immunohistochemistry, and protein affinity purification (including multiple markers, immobilized binding agents, and polyclonal antibodies) Aruffo et al. teaches methods of sorting using monoclonal antibodies, as well as DNA analysis and Southern Blot, and including the cell adhesion molecule CD2. Heller et al., teaches DNA analysis of selected cells using micro array design. Foote, US Patent 5,661,628 teaches an example a microchip used for DNA analysis and methods of using such. (see for

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abstract and entire document). Thus the specific methods of sorting and analyzing cells were known in the art, as set forth and exemplified above.

Therefor it would have been prima facie obvious to one of skill in the art to sort and analyze the olfactory (serpentine) marker expressing cells, and one would have been motivated to do so to test for olfactory, sperm chemotaxis, or neurological function.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**anthony.caputa@uspto.gov**].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly


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signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

July 30, 2001

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

**Attachment for PTO-948 (Rev. 03/01, or earlier)**  
**6/18/01**

**The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.**

**INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

**1. Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.